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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,525	07/28/2003	Peter Keeling	15056-4	4291
29137	7590	09/23/2005	EXAMINER	
BASF CORPORATION CARL-BOSCH-STRASSE 38 LUDWIGSHAFEN, D67056 GERMANY			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,525

Applicant(s)

KEELING ET AL.

Examiner

Samuel W. Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11,13-17 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-11, 13-15 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

Claims 10-11, 13-17 and 21 are pending.

The amendment filed 6/30/05, which cancels claims 6-9 and 12, amends claims 10-11, 13-14 and adds claim 21 has been entered. Note that claims 1-6 and 18-20 were canceled by applicants' amendment filed 7/28/03.

The following section states the reason of the restriction requirement for the previous pending claims 7-17 set forth in the previous Office action mailed 3/28/05.

Election/restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 7-15, drawn to a polynucleotide, an expression vector comprising the polynucleotide, and a host cell comprising the vector, are classified in class 536, subclass 23.1, class 435, subclass 320.1 and 69.1.

II. Claims 16-17, drawn to a plant and a seed from the plant, are classified in class 800, subclasses 295 and 298.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention I is drawn to polynucleotide whereas Invention II to a multicellular organism, plant. The compositions of Inventions I and II are structurally and functionally distinct, and are capable of separate manufacture or use.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

Claims 16-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 10-11, 13-15 and 21 are examined in this Office action.

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 10-11, 13-15 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites (i) "a nucleotide sequence encoding a transit peptide", (ii) a nucleic acid encoding starch-encapsulating region", and (iii) a nuclei acid encoding the payload polypeptide"; the recitations are indefinite because recitation does not make it clear that whether or not the nucleotide sequences or the nucleic acids thereof (i) to (iii) is placed in a random order, and because the specification does not provide a clear-cut definition for structural characteristics of the starch-encapsulating region; what is sequence of said region existing in starch synthase or starch branching enzyme or granule bound starch synthase (see page 8, the 3rd paragraph of specification). The dependent claims are also rejected.

Applicants' response to the rejection under 35 USC 112, second paragraph.

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The response filed 6/30/05 argues that one skilled in the art can figure out from the concept of starch binding domain the starch-encapsulating region (SER) (see page 7, the 3rd paragraph), and that Examples 1 and 7 teach the SER. The applicants' argument is found to be unpersuasive because the structure of SER should not be based on the concept, and because neither Example 1 nor Example 7 teaches the structural or sequence of SER but rather, Example 1 teach a procedure for selecting the SER region (see pages 25-26).

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-11, 13-15 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant application (see newly added independent claim 21) is directed to a polynucleotide comprising a nucleotide sequence encoding a transit peptide, a nucleotide sequence encoding starch-encapsulating region (SER), and a nucleotide sequence encoding the payload polypeptide (of interest). The specification does not teach each sequences indicated above. In the absence of the nucleotide sequences thereof, e.g., the SER sequence and transit peptide sequence, one skilled in the art would be unable to practice the claimed invention. For example, the SER could be searched in any starching-binding enzymes, e.g., starch synthase, starch branching

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enzyme and granule bound starch synthase (see the page 8 of the specification).

Furthermore, transit peptides contain multiple domains that provide either distinct or overlapping functions, e.g., direct interaction with envelope lipid, chloroplast receptors and the stromal processing peptidase; and, as yet, the transit peptides are still poorly characterized (see the Bruce reference in *Trends Cell Biol.* (2000) 10, 440-4447, especially abstract). Hence, without description or teaching with regard to the above-mentioned nucleotide sequences, one skilled in the art are not in possession of the claimed polynucleotide, the vector comprising the polynucleotide and the host cell comprising the vector. Therefore, the current application lacks written description for the claimed compositions.

Claim rejections under 35 USC §102 and §103 previously stated in the Office action mailed 3/28/05 are withdrawn as the patents 5977437 and 6307125 do not fairly teach or suggest the subject matter, i.e., a recombinant nucleotide sequence comprising (i) the promoter, (ii) the nucleotide sequence encoding a transit peptide, (iii) the nucleic acid encoding starch-encapsulating region, and (iii) the nucleic acid encoding the payload polypeptide disclosed in the new claim 21 (an independent claim).

Conclusion

No claims are allowed

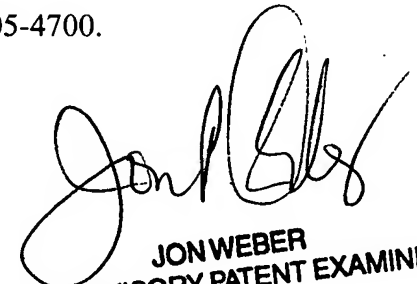
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach

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the examiner by telephone are unsuccessful, the examiner's supervisor, Weber, Jon, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, Ph.D.
Art Unit 1653, Examiner
September 16, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER